

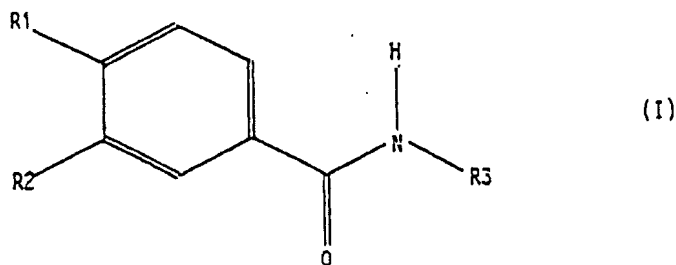
Appendix A

Claim Amendments

This listing of claims will replace all prior versions, and listings, of claims in the application.

1.- 17. (Canceled)

18. (Previously presented) A solid dosage form in tablet or pellet form for oral administration of a PDE 4 inhibitor, comprising a PDE 4 inhibitor together with polyvinylpyrrolidone as binder, and one or more other suitable pharmaceutical excipients, wherein the PDE 4 inhibitor is a compound of the formula I



in which

R1 is difluoromethoxy,

R2 is cyclopropylmethoxy and

R3 is 3,5-dichloropyrid-4-yl,

or a salt of this compound, an N-oxide of the pyridine of this compound or a salt thereof, wherein said dosage form has

immediate release of the PDE 4 inhibitor, and wherein the polyvinylpyrrolidone is selected from the group consisting of polyvinylpyrrolidone of molecular weight 28,000 - 34,000, polyvinylpyrrolidone of molecular weight 44,000 - 54,000 and polyvinylpyrrolidone of molecular weight 1,000,000 - 1,500,000.

19. (Previously presented) The dosage form as claimed in claim 18, wherein the PDE 4 inhibitor is N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide (roflumilast).

20. (Previously presented) The dosage form as claimed in claim 18, wherein the PDE 4 inhibitor is the N-oxide of the pyridine of the compound of formula I.

21. (Previously presented) The dosage form according to claim 19 containing from 0.01 mg to 5 mg of roflumilast per dosage unit.

22. (Previously presented) The dosage form according to claim 18, wherein the proportion of polyvinylpyrrolidone is from 1 to 5% by weight.

23. (Previously presented) The dosage form according to claim 18, wherein the proportion of polyvinylpyrrolidone is from 2 to 3% by weight.

24. (Canceled)

25. (Previously presented) The dosage form as claimed in claim 18, where the pharmaceutical excipients are excipients selected from the group consisting of fillers, additional binders, tablet disintegrants, lubricants, release agents, flavouring substances, buffer substances, preservatives, coloring substances and emulsifiers.

26. (Previously presented) The dosage form according to claim 18, wherein the proportion of all binders present is from 0.5 to 20% by weight.

27. (Previously presented) The dosage form according to claim 25, which is a tablet and wherein the proportion of filler is from 40 to 99% by weight.

28. (Previously presented) The dosage form as claimed in claim 25, wherein the filler is selected from the group consisting of sugar alcohols, starches, saccharides and mixtures thereof.

29. (Previously presented) The dosage form as claimed in claim 28, wherein the filler is selected from the group consisting of corn starch, microcrystalline cellulose, lactose and mixtures thereof.

30. (Previously presented) The dosage form according to claim 25, wherein the lubricant or release agent is selected from the group consisting of sodium stearyl fumarate, magnesium stearate, calcium stearate, stearic acid, talc and colloidal anhydrous silica.

31. (Previously presented) The dosage form as claimed in claim 18, which is a tablet.

32. (Previously presented) The dosage form as claimed in claim 31, wherein the pharmaceutical excipients are at least one filler and at least one lubricant or release agent.

33. (Currently amended) The dosage form as claimed in claim 31, comprising

- |  |           |
|--|-----------|
| 1. Roflumilast   | 0.125 mg  |
| 2. Lactose monohydrate   | 49.660 mg |
| 3. Corn starch   | 13.390 mg |
| 4. <del>Polyvidone K90</del> <u>polyvinylpyrrolidone of molecular weight</u><br><u>1,000,000 - 1,500,000</u> | 1.300 mg  |
| 5. Magnesium stearate (vegetable)  | 0.650 mg. |

34. (Currently amended) The dosage form as claimed in claim 31, comprising

1. Roflumilast 0.250 mg
2. Lactose monohydrate 49.660 mg
3. Corn starch 13.390 mg
4. ~~Polyvidone K90~~ polyvinylpyrrolidone of molecular weight  
1,000,000 - 1,500,000 1.300 mg
5. Magnesium stearate (vegetable) 0.650 mg.

35. (Currently amended) The dosage form as claimed in claim 31, comprising

1. Roflumilast 0.500 mg
2. Lactose monohydrate 49.660 mg
3. Corn starch 13.390 mg
4. ~~Polyvidone K90~~ polyvinylpyrrolidone of molecular weight  
1,000,000 - 1,500,000 1.300 mg
5. Magnesium stearate (vegetable) 0.650 mg.

36. (Previously presented) The dosage form according to claim 18, comprising a solid solution of the PDE 4 inhibitor in the binder PVP as carrier.

37. (Previously presented) The dosage form according to claim 36, wherein the solid solution is a solid solution with amorphous structure, in which the PDE 4 inhibitor is in the form of a molecular dispersion in the carrier material.

38. (Previously presented) The process for producing a dosage form as claimed in claim 18, comprising the steps:  
(a) producing a mixture of PDE 4 inhibitor of formula I and one or more pharmaceutical excipients and (b) granulating the mixture obtained in (a) with an aqueous solution of polyvinylpyrrolidone.

39. (Previously presented) The process according to claim 38, further comprising:

- (a) drying the granules,
- (b) optionally admixing other pharmaceutical excipients,
- (c) mixing with a release agent and
- (d) compressing in a tablet press.

40. (Previously presented) The process according to claim 38, further comprising processing wet preparations obtained after granulating to pellets.

41. (Previously presented) The process according to claim 38, wherein the granulating takes place in a fluidized bed granulator.

42. (Previously presented) The process according to claim 38, wherein in step (a) the PDE 4 inhibitor is admixed with other pharmaceutical excipients in the form of a trituration with a

pharmaceutical excipient.

43. (Previously presented) The process according to claim 42, which trituration is obtained by grinding the PDE 4 inhibitor with a pharmaceutical excipient.

44. (Previously presented) The process according to claim 42, wherein the pharmaceutical excipient is a filler.

45. (Previously presented) The process according to claim 38, comprising granulating a mixture of (a) a PDE 4 inhibitor of formula I, or a trituration of a PDE 4 of formula I with corn starch, (b) corn starch and (c) lactose monohydrate with an aqueous polyvinylpyrrolidone solution to form granules, drying the granules, mixing the granules with a release agent and compressing the granules in a tablet press.

46. (Previously presented) The process according to claim 38, comprising granulating a mixture of (a) a PDE 4 inhibitor of formula I, or a trituration of a PDE 4 of formula I with corn starch, (b) corn starch, (c) microcrystalline cellulose and (d) sodium carboxymethylstarch with an aqueous polyvinylpyrrolidone solution to form granules, drying the granules, mixing the granules with a release agent and compressing the granules in a tablet press.

47. (Previously presented) A process for producing a dosage form as claimed in claim 18, comprising the steps:

(a) producing a mixture of pharmaceutical excipients, (b) granulating the mixture obtained in (a) with a suspension of the PDE 4 inhibitor of formula I in an aqueous solution of PVP.

48. (Previously presented) The process according to claim 47, comprising granulating a mixture of corn starch and lactose monohydrate with a suspension of a PDE 4 inhibitor of formula I in an aqueous solution of PVP to form granules, drying the granules, mixing the granules with a release agent and compressing the granules in a tablet press.

49. (Previously presented) A process for producing a dosage form as claimed in claim 18, comprising producing a solid solution of polyvinylpyrrolidone and a PDE 4 inhibitor of formula I, comprising the following steps:

(a) dissolving PVP and a PDE 4 inhibitor of formula I in a solvent, and

(b) removing the solvent from the solution of PVP and PDE 4 inhibitor.

50. (Previously presented) The process according to claim 49, wherein the solid solution is a solid solution with amorphous structure in which the PDE 4 inhibitor of formula I is in the form of a molecular dispersion in polyvinylpyrrolidone.



51. (Previously presented) The process according to claim 49, wherein the solid solution is produced by a solvent method in which polyvinylpyrrolidone, the PDE 4 inhibitor and optionally other pharmaceutical excipients are dissolved in a solvent, and wherein the solvent is subsequently removed again by spray drying, normal drying, vacuum drying or freeze-drying.

52. (Previously presented) The process according to claim 49, wherein the solid solution is produced by a mixing method in which the PDE 4 inhibitor and where appropriate other pharmaceutical excipients are vigorously mixed together with polyvinylpyrrolidone.

53. (Previously presented) A process for producing a dosage form according to claim 18, comprising the steps: (a) producing an active ingredient preparation in the form of a solid solution in polyvinylpyrrolidone of a PDE 4 inhibitor of formula I, (b) producing a mixture of an active ingredient preparation and pharmaceutical excipients and (c) granulating the mixture obtained in (b) with an aqueous solution of polyvinylpyrrolidone.

54. (Previously presented) The process according to claim 53 for producing a dosage form in the form of a tablet, wherein the granules obtained in step (c) are dried, mixed with

lubricants or release agents and compressed in a tablet press.

55. (Previously presented) The process according to claim 53 for producing a dosage form in the form of pellets, wherein the wet granules obtained in step (c) are produced by an extruder/spheronizer process to suitable pellets.

56. (Previously presented) A process for producing a dosage form according to claim 18 in the form of pellets, wherein dispersions/suspensions of an active ingredient preparation are applied in the form of a solid solution in polyvinylpyrrolidone of a PDE 4 inhibitor in a solvent to pellet-like carriers.

57. (Previously presented) The process according to claim 56, wherein the pellet-like carriers are nonpareils or HPMC-containing pellets.

58. (Previously presented) A method for the treatment of a disease regarded as treatable by PDE 4 inhibitors, wherein a dosage form according to claim 18 is administered.

59. (Previously presented) The method of treatment according to claim 58, wherein the disease is selected from the group consisting of asthma and airway obstructions.

60. (Previously presented) The method of treatment according to

claim 59, wherein the disease is COPD (chronic obstructive pulmonary disease).

61. (Previously presented) The dosage form according to claim 19 containing from 0.05 mg to 2.5 mg roflumilast per dosage unit.

62. (Previously presented) The dosage for according to claim 19 containing from 0.1 mg to 0.5 mg of roflumilast per dosage unit.

63. (Previously presented) The dosage form according to claim 25, which is a tablet and wherein the proportion of filler is from 60 to 97% by weight.

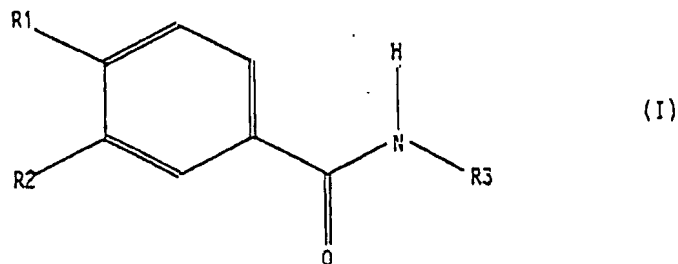
64. (Previously presented) The dosage form as claimed in claim 25, wherein the filler is selected from the group consisting of calcium carbonate, sodium carbonate, mannitol, sorbitol, xylitol, maltitol, corn starch, potato starch and wheat starch, microcrystalline cellulose, glucose, lactose, lactose monohydrate, levulose, sucrose, dextrose and mixtures thereof.

65. (Previously presented) The process according to claim 43, wherein the pharmaceutical excipient is a filler.

66. (Previously presented) The dosage form as claimed in claim

18, wherein the polyvinylpyrrolidone has a molecular weight of 1,000,000 - 1,500,000.

67. (Currently amended) A solid dosage form in tablet or pellet form for oral administration of a PDE 4 inhibitor, comprising a PDE 4 inhibitor together with polyvinylpyrrolidone as binder, and one or more other suitable pharmaceutical excipients, wherein the PDE 4 inhibitor is a compound of the formula I



in which

R1 is difluoromethoxy,

R2 is cyclopropylmethoxy and

R3 is 3,5-dichloropyrid-4-yl,

or a salt of this compound, an N-oxide of the pyridine of this compound or a salt thereof, wherein said dosage form has immediate release of the PDE 4 inhibitor, and wherein the polyvinylpyrrolidone is ~~Polyvidone-K90~~ polyvinylpyrrolidone of molecular weight 1,000,000 - 1,500,000.